



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

July 18, 2017

Aaron Johnson, DVM, MS  
Senior Research Scientist  
Elanco Animal Health  
2500 Innovation Way  
Greenfield, IN 46140

Subject: Label Amendment – Revisions to organization and mitigation  
Product Name: EasySpot For Cats  
EPA Registration Number: 70585-11  
Application Date: 1-Sep-16  
Decision Number: 521113

Dear Dr. Johnson:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, you may contact Julie Breeden-Alemi, DVM at 703-347-0511 or via email at [Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Elizabeth Fertich". The signature is written in a cursive style with a large initial "E".

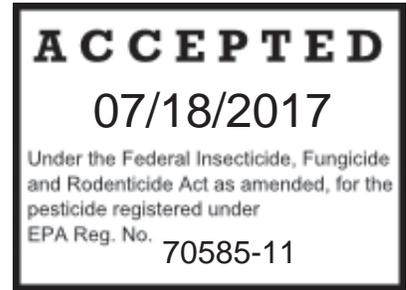
Elizabeth Fertich  
Acting Product Manager 03  
Invertebrate & Vertebrate Branch 1  
Registration Division (7505P)  
Office of Pesticide Programs

Enclosure

[Optional text appears in brackets -the final label may include some or all of the optional text on front, back, side, or inside label panels]

CARTON FRONT PANEL

**EasySpot™**  
**For Cats**  
[(fipronil)]



{Note to Reviewer: The word "Cats" will be included in the product name and will be at least 75% the height of the largest letter in the product name.}

A large, clear picture of a cat in the weight range for the product as packaged will be on the front panel.

[A][a]pply only to kittens more than 8 weeks old and over 1.5 lbs  
[[*alternate language*] [A][a]pply only to kittens 8 weeks or older and over 1.5 lbs]

{Note to Reviewer: See Optional Marketing Claims list at the end of the label.}

**ACTIVE INGREDIENTS:**

Fipronil ..... 9.7 %

**INERT INGREDIENTS:** ..... 90.3%

**TOTAL:** ..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

See Back [Panel] [Label Panel] for full Directions for Use, First Aid and Precautionary Statements

**NET CONTENTS:**

[1][One][2][Two] [Three] [3] [Four][4][5][Five][6][Six][12][Twelve][24][Twenty-Four] [-]  
0.017 fl oz (0.50ml) tube[s]

## CARTON BACK PANEL

[EasySpot™ [For Cats]] contains fipronil to effectively kill fleas and ticks [(including those that may transmit Lyme disease)].

### **READ ENTIRE LABEL BEFORE EACH USE**

[EasySpot™ [For Cats] provides [four-] [three-] way protection that kills [fleas], [ticks], [mosquitoes] and [chewing lice]. Kills deer ticks [that may transmit Lyme disease]. Kills brown dog ticks, American dog ticks and lone star ticks. Prevents flea reinfestation.]

#### **Side Effects**

Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching, or other signs of discomfort. If signs of a sensitivity occur, bathe your cat with a mild soap and rinse with large amounts of water. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these or other side effects occur, consult your veterinarian or Elanco US, Inc. at 1-888-545-5973. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application.

{Note to Reviewer: A box labeled "Side Effects" will be placed at the lower right hand corner of the back panel. }

For Technical Information call: 1-888-545-5973 [hours of service]  
[Manufactured in the USA] [Formulated in the USA]

[Distributed by] [Manufactured for][Available exclusively from]:  
Elanco US, Inc.  
2500 Innovation Way  
Greenfield, IN 46140

[BAR CODE AREA]

EPA Reg. No. 70585-11  
EPA Est. NO. XXXXX-XX-XXX

**INSIDE FLAP OF CARTON BACK PANEL**

<b>FIRST AID</b>	
If swallowed	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes	Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If on skin	Wash with plenty of soap and water. Get medical attention if irritation persists.
<b>HOTLINE NUMBER</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-888-545-5973.	

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS. CAUTION.** Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS.** For external use only. Individual sensitivities, while rare, may occur after using any pesticide product on cats. Certain medications can interact with pesticides. Do not treat your cat with more than one topically applied pesticide product at a time. Overdosing your cat can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated or aged cats. Can be used on breeding, pregnant, or lactating [cats][female cats][queens]. Consult a veterinarian before using on cats with known organ dysfunction.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**Do not allow children to apply product.**-TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. Do not allow your cat to ingest this product.- Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than 1.5 lbs. Do not apply more than one tube per treatment for one cat regardless of the cat's weight. In multiple cat households do not allow cats to groom each other until the

product has dried. Use entire contents of [tube] [vial] on each cat. [Do not split one tube between two cats.] Do not bath cats until 24 hours after application.

**[(INSERT DIAGRAM THAT DEPICTS APPLICATION OF PRODUCT ON THE CAT)]**

**How to Open:** Remove product [tube[s]] [vial[s]] from the package. [Separate one tube from the others.] Hold the [tube] [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

**How to apply:** While holding the cat with one hand, use the other hand to apply the solution. Invert the [tube] [vial] and use the open end to part the cat's hair. Apply contents of one [tube] [vial] of EasySpot™ [For Cats] [as a spot between the shoulder blades] [as a stripe, starting high on the back of the cat's neck to in front of the shoulder blades]. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat. When finished, wrap the [tube] [vial] in paper and put into the trash. Apply only one tube per cat per treatment. Repeat application may be made if necessary, but do not apply more often than once every 30 days.

[Optional drawings of application process that may or may not appear on finished label]

**FREQUENCY OF APPLICATION**

Use EasySpot™ [For Cats] monthly for control of [flea], [tick] [and] [chewing lice] [and mosquito] infestations. [Studies show that] EasySpot™ [For Cats] kills fleas for up to six weeks. If your cat is at high risk for flea reinfestation [or in a highly infested environment], apply monthly. Apply monthly to control [ticks], [mosquitoes] and [chewing] [lice]. [ EasySpot™ [For Cats] Kills mosquitoes [within 48 hours for up to 1 month]] EasySpot™ [For Cats] remains effective after water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for 30 days.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE:** Do not remove tube from the pack until ready to use. Store in a cool (below 77°F [25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container.

If empty: Place in the trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

**WARRANTY**

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of ELANCO US, INC. (EUS) or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold EUS and Seller harmless for any claims relating to such factors.

EUS warrants that this product conforms to the chemical description on the label and is reasonably fit for the purpose stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or EUS, and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, EUS MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with State law, in no event shall EUS or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF EUS AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF EUS OR SELLER, THE REPLACEMENT OF THE PRODUCT.

[If you have questions or comments about this product, please write to: Elanco US, Inc., (address).]

## OPTIONAL TEXT FOR CARTON BACK PANEL OR INSIDE FLAP OF CARTON BACK PANEL

{Note to Reviewer: text in the following section may be used in addition to, not as a replacement for, the required text shown in carton back panel and inside flap of carton back panel sections above.}

**How to Apply - May contain graphics illustrating product use, e.g., cat with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.**

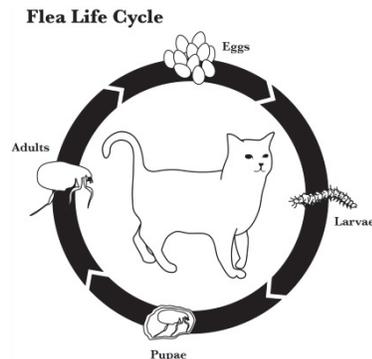
### **How to Open:**

1. Remove product [tube[s]] [vial[s]] from package.
2. [Separate one [tube] [vial] from the others.] Hold the [tube] [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

### **How to Apply:**

1. Invert [tube] [vial] over cat and use open end to part cat's hair.
2. Apply contents of one [tube] [vial] of EasySpot™ [For Cats] [as a spot between the shoulder blades] [as a stripe, starting high on the back of the cat's neck to in front of the shoulder blades].
3. Squeeze [tube] [vial] firmly to apply all of the solution to the cat's skin.

**Example Flea life cycle diagram – actual may differ slightly**



Look at the Label (Look at the Label icon)

[Easy] [6] [Six-] [Step] EasySpot™ [For Cats] [Spot-on] [Squeeze-On] Checklist

1. Read the label completely and follow directions.
2. Weigh your cat.
3. Do NOT use dog products on cats.
4. Do NOT treat with more than one pesticide product at a time.
5. To avoid chance of ingestion, separate treated cats from each other and other pets until product is dry.
6. Do NOT split tubes between cats.

For year round protection, apply EasySpot™ [For Cats] monthly.

Cat's Name (Empty blank for owner to fill in name)

First [dose] [Treatment] (Empty blank for owner to fill in date)

Second [dose] [Treatment] (Empty blank for owner to fill in date)  
 Third [dose] [Treatment] (Empty blank for owner to fill in date)  
 Fourth [dose] [Treatment] (Empty blank for owner to fill in date)  
 Fifth [dose] [Treatment] (Empty blank for owner to fill in date)  
 Sixth [dose] [Treatment] (Empty blank for owner to fill in date)  
 Seventh [dose] [Treatment] (Empty blank for owner to fill in date)  
 Eighth [dose] [Treatment] (Empty blank for owner to fill in date)  
 Ninth [dose] [Treatment] (Empty blank for owner to fill in date)  
 Tenth [dose] [Treatment] (Empty blank for owner to fill in date)  
 Eleventh [dose] [Treatment] (Empty blank for owner to fill in date)  
 Twelfth [dose] [Treatment] (Empty blank for owner to fill in date)

Calendar stickers [with EasySpot™ [For Cats]

[1] [2] [3] [4] [5] [6] [12] [24]-month] [application tracker

For year-round protection, apply EasySpot™ [For Cats] monthly. Place stickers on your calendar as a reminder to reapply EasySpot™ [For Cats] in 30 days.

It's time for EasySpot™ [For Cats] [!]

Enclosed for your convenience [is] [are] [1] [one] [2] [two] [3] [three] [4] [four] [5] [five] [6] [six] [12] [twelve] [24] [twenty-four] sticker[s].] [Place stickers on your calendar every 30 day from initial treatment as a reminder to reapply EasySpot™ [For Cats] every 30 days.

Optional Example graphics for calendar stickers and/or magnets.

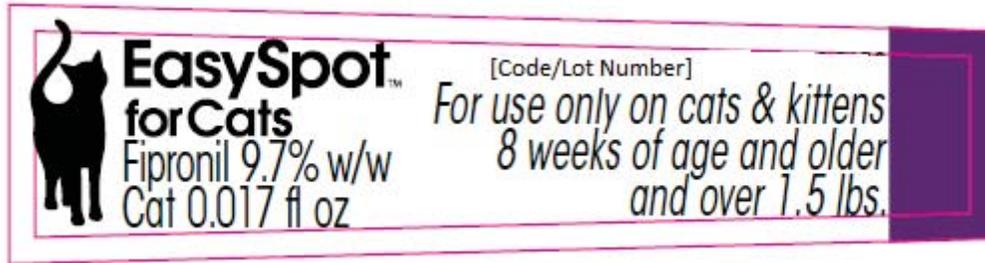


Monthly Application Reminder Magnet (image of reminder magnet)

Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply EasySpot™ [For Cats]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.

TUBE LABEL

[FRONT OF TUBE]



[BACK OF TUBE]

KEEP OUT OF REACH OF CHILDREN

CAUTION: Read accompanying directions and precautions before using. Use scissors to open.

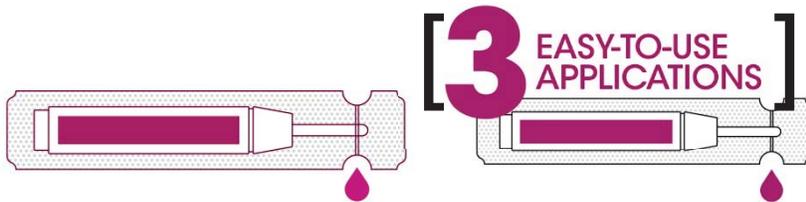
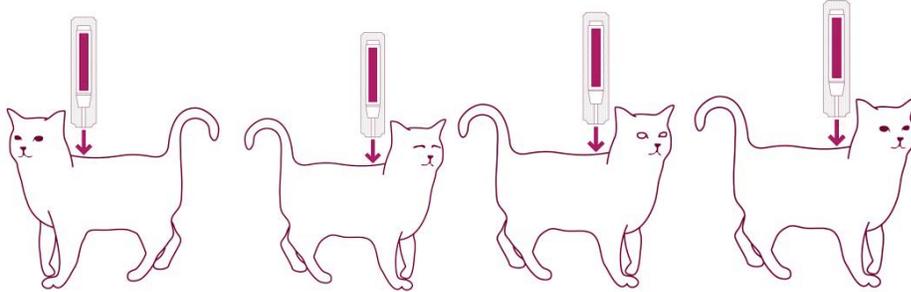
EPA REG. No. 70585-11

EPA EST. NO. XXXXX-XXX-XXX

{label code}

## OPTIONAL LABEL GRAPHICS

[Example pictograms that may or may not be found on the printed label]



**[3 EASY-TO-USE APPLICATIONS]**

**[[1] [2] [4] [5] [6] [12] [24]  
EASY-TO-USE  
APPLICATIONS]**

## OPTIONAL MARKETING CLAIMS

### Mosquitoes

1. Kills mosquitoes [within 48 hours for up to 1 month]

### Adult Fleas

1. Kills adult fleas [for up to six weeks] [!]
2. Kills newly emerged adult fleas before they lay eggs
3. Kills fleas, a source of flea allergy dermatitis [, flea bite anemia]
4. If cat is a high risk for flea reinfestation, apply a once a month application
5. Kills fleas [[for] up to [4 weeks] [1 month] [30 days] [!]]

### Ticks

1. Kills ticks, including those that may carry Lyme disease
2. Kills ticks [for up to [[4] [four] weeks] [1 month] [30 days]!]
3. Kills deer ticks [[that may carry Lyme disease,] [for up to [[4] [four] weeks] [1 month] [30 days]]
4. Kills ticks
5. Kills brown dog ticks
6. Kills lone star ticks
7. Kills ticks (including deer ticks) for up to [[4] [four] weeks] [1 month] [30 days]
8. Kills [brown], [American dog,] [and] [lone star,] ticks [(*Rhipicephalus sanguineus*)] for up to [[4] [four] weeks] [1 month] [30 days]
9. Kills American dog ticks [(*Dermacnitor variabilis*)] for up to [[4] [four] weeks] [1 month] [30 days][!]

### Multiple Infestations

1. Kills chewing lice [and] [[C][c]ontrols mites that may cause sarcoptic mange [infestations]
2. Flea [&] [and] tick control only for cats [&] [and] kittens 8 weeks old and older and over 1.5 lbs.
3. Flea [&] [and] tick control only for cats [&] [and] kittens more than 8 weeks old and over 1.5 lbs.
4. Kills [fleas], [ticks], [chewing lice] [&] [and] [mosquitoes]
5. Kills [fleas], [ticks], [mosquitoes] [and] [&] [chewing lice]
6. Monthly [flea], [tick], [mosquito], and [chewing lice] treatment
7. [Four] [4] way control - kills fleas, ticks, mosquitoes and chewing lice
8. [Three] [3]way control - kills fleas, ticks, and chewing lice
9. [[4] [four] [-] week] [1 month] [30 day] [flea] [and] [tick] treatment
10. [[4] [four] [-] week] [1 month] [flea], [tick], [mosquito] [and] [chewing lice] control
11. Once-a-month [flea] [and] [tick] treatment
12. Use EasySpot™ [For Cats] monthly to control [fleas] [ticks] and [chewing lice]
13. Monthly [flea], [tick], [mosquito] [and] [chewing lice] protection.

14. Kills [fleas] and [ticks] for up to [4] [four] weeks] [1 month] [30 days]!
15. EasySpot™ [For Cats] provides [convenient] [and] [effective] [flea], [tick] [,] [&] [and] [chewing lice] [and mosquito] control for cats and kittens 8 weeks and older and over 1.5 lbs.

#### All Others

1. For use only on cats [and kittens more than 8 weeks old and over 1.5 lbs]
2. For use only on cats [and kittens 8 weeks old and older and over 1.5 lbs]
3. Waterproof
4. Fast [-] acting
5. Long [-] lasting
6. Prevents [flea] reinfestation
7. Convenient spot treatment
8. Once-a-month treatment
9. A once monthly application for chewing lice
10. Fast action against [chewing] lice infestations
11. [One] [Two] [Three] [Four] [Five] [Six] [Twelve] [Twenty-Four] applications] and/or [ [1] [2] [3] [4] [5] [6] [12] [24] -month supply] or [[4] [8] [12] [16] [20] [24] -week supply] or [[1] [2] [3] [4] [5] [6] [12] [24] applications]
12. Best if used year round!
13. 4[-]week dose[!][in Child Resistant Packaging]
14. 1[-]month dose[!][in Child Resistant Packaging]
15. 30[-]day dose[!][in Child Resistant Packaging]
16. Easy-to-use [application]
17. Formulated only for cats and kittens older than 8 weeks and over 1.5 lbs
18. fipronil (9.7%)
19. A fipronil product
20. Contains fipronil[, ] [-] the active ingredient in Fipaira for Cats\*
21. \*EasySpot™ [For Cats]] is not manufactured by or distributed by Merial. Fipaira for Cats is a registered trademark of Merial.  
{Note to Reviewer: When the two statements above (with \*) are used, both statements will be used and they will appear on the same panel}
22. Fast-acting, long-lasting that's also waterproof.
23. [One][1][Two][2][Three][3][4][Four][5][Five][Six][6][Twelve][12][Twenty-Four][24]] [Easy to Use] Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][Four Month Supply][Five Month Supply][6 month Supply][12 Month Supply][24 month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week Supply] [20 Week Supply][24 Week Supply] [in Child Resistant Packaging]
24. Easy-to-use [application]
25. [Free] calendar stickers inside!
26. [Free] calendar stickers inside
27. Apply once every [4 weeks] [month] [30 days]!
28. Can be used on breeding, pregnant and lactating [cats] [queens] [female cats]
29. [Free] Monthly application reminder magnet inside
30. Can be used only on kittens more than 8 weeks of age and over 1.5 lbs.
31. Can be used only on kittens 8 weeks of age and older and over 1.5 lbs.

32. Optional graphics: picture of flea, tick, chewing lice, mosquito with line through them
33. Protection [P][p]ack
34. Cats know what they want. You know what they need.
35. This protection pack contains [1] [2] [3] [4] [5] [6] [12] [24] [a single] dose[s] of EasySpot™  
[For Cats], along with other valuable offers to help ensure that your cat is always protected.

EPA [*approval date*]